

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON,

Plaintiff,

v.

Civil Action No. 3:17-01362

AMERISOURCEBERGEN DRUG  
CORPORATION, et al.,

Defendants.

v.

Civil Action No. 3:17-01665

CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG  
CORPORATION, et al.,

Defendants.

**MEMORANDUM OPINION AND ORDER**

Pending before the court is defendants' renewed motion to exclude the opinions of James E. Rafalski. (ECF No. 1385.) For the reasons that follow, the court will grant the motion in part. The court will exclude the causation opinions but not the opinions regarding potential flagging methods, the results thereof, and whether defendants' suspicious order monitoring systems were effective.

**I. Background**

James Rafalski ("Rafalski") worked as an investigator for the Drug Enforcement Agency ("DEA") for thirteen years. When he joined the DEA in 2004, he brought with him twenty-six years of law enforcement experience. Judge Polster has described Rafalski's role at the DEA as follows:

Diversion Investigators are responsible for conducting regulatory, state, civil, administrative, and criminal investigations. From 2011 to 2017, Rafalski was primarily responsible for conducting administrative, civil, and regulatory investigations of DEA registrants. In this capacity, he investigated the criminal conduct of individual physicians regarding improper opioid prescriptions and conducted regulatory investigations involving, inter alia, Distributors' compliance with DEA requirements regarding suspicious order monitoring systems ("SOMS").

For example, in 2006, Rafalski conducted an accountability audit, record-keeping review, and security investigation of a Walgreens in Ohio to ensure compliance with controlled substances regulations and record keeping. This investigation resulted in the DEA issuing a letter of admonition for the maintenance of an inadequate SOMS.

From 2010 to 2013, Rafalski conducted an administrative investigation of The Harvard Drug Group to identify unusual patterns of distribution of oxycodone to Florida pain clinics. His work included the review of company records and policies, as well as the DEA's ARCOS data. This investigation resulted in the DEA issuing an order to show cause for, inter alia, developing a work-around to avoid triggering the company's SOMS.

Also, from 2010 to 2013, Rafalski conducted an administrative investigation of Masters Pharmaceutical, reviewing company files regarding customer due diligence, including questionnaires, on-site investigation reports, and SOMS information.

This investigation resulted in the DEA revoking the company's registration to manufacture and/or distribute controlled substances.

From 2010 to 2017, Rafalski conducted an administrative investigation of Mallinckrodt in which he reviewed chargeback data that revealed some pharmacies and/or practitioners were utilizing multiple Distributors to purchase the same product in large quantities. As a result of this investigation, the DEA and Mallinckrodt entered into a three-year Memorandum of Agreement.

In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 3934490, at \*1-2 (N.D. Ohio Aug. 20, 2019) (citations omitted).

## **II. Legal Standard**

Federal Rule of Evidence 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

"Essentially, the witness must be qualified as an expert, the testimony must be reliable, and the testimony must assist the

trier of fact.” In re Fosamax Prod. Liab. Litig., 645 F. Supp. 2d 164, 172 (S.D.N.Y. 2009).

Rule 702 requires courts to stop proffered expert opinions at the gate if they lack reliable foundation or relevance “to the task at hand.” McKiver v. Murphy-Brown, LLC, 980 F.3d 937, 959 (4th Cir. 2020). Because “the adversary system” awaits such opinion evidence on the other side of the gate, the gatekeeping function is a limited one. See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. 892 F.3d 624, 631 (4th Cir. 2018). Beyond the gate are credibility determinations, which are reserved for the trier of fact; before the gate are reliability and relevancy determinations, which are the province of the gatekeeper. Sardis v. Overhead Door Corp., 10 F.4th 268, 282 (4th Cir. 2021) (“[C]redibility is entirely distinct from reliability and relevancy, which are *preconditions* to the admissibility of expert testimony.”) (emphasis in original).

Factors that may guide the court in the fulfillment of its gatekeeping role include

(1) whether the particular scientific theory can be (and has been) tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; and (5) whether the technique has achieved general acceptance in the relevant scientific or expert community.

United States v. Crisp, 324 F.3d 261, 265-66 (4th Cir. 2003) (citations and internal quotation marks omitted). This list is illustrative, not definitive or exhaustive. Id.

In Kumho Tire Co. v. Carmichael, the Supreme Court held that the gatekeeping function extends beyond the scientific realm "to the testimony of engineers and other experts," but the Court made clear that the Daubert analysis should suit the proffered opinion. 526 U.S. 137, 141 (1999). That is, although "a trial court may consider one or more of the more specific factors that Daubert mentioned when doing so will help determine that testimony's reliability," it need not tick through Daubert's factors because they "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Id. at 150 (emphasis in original); see also In re Mirena IUD Prod. Liab. Litig., 169 F. Supp. 3d 396, 480 (S.D.N.Y. 2016) ("[T]he four-factor mold set forth by Daubert that governs scientific expert opinions," does not necessarily apply to non-scientific expert opinions.). The factors, in short, are not "holy writ." See Kumho, 526 U.S. at 159 (Scalia, J., concurring).

The Fourth Circuit has also reiterated that "trial courts are typically given 'broad latitude' to determine which of these factors (or some other unspecified factors) are 'reasonable

measures of reliability in a particular case.'" Sardis, 10 F.4th 268, 281 (emphasis added) (quoting Nease v. Ford Motor Co., 848 F.3d 219, 229 (4th Cir. 2017)). In other words, it is neither mandatory nor advisable to shoehorn every reliability analysis into the four "guideposts" set forth in Daubert. Id.

The reliability of the methodology, not the correctness of the conclusion, is the focus of the Daubert inquiry. See Pugh v. Louisville Ladder, Inc., 361 F. App'x 448, 452 (4th Cir. 2010).

[D]istrict courts must ensure that an expert's opinion is based on scientific, technical, or other specialized *knowledge* and not on belief or speculation. And to the extent an expert makes inferences based on the facts presented to him, the court must ensure that those inferences were derived using scientific or other valid methods.

Sardis, 10 F.4th at 281 (emphasis in original) (citation omitted).

Helpfulness to the trier of fact is the "touchstone" of Rule 702. Kopf v. Skyrn, 993 F.2d 374, 377 (4th Cir. 1993). The party proffering the expert's opinion has the burden of production on the question of admissibility. Maryland Cas. Co. v. Therm-O-Disc, Inc., 137 F.3d 780, 783 (4th Cir. 1998).

### **III. Analysis**

Rafalski formulated six methods that could potentially be used to flag suspicious orders, referring to them as Methods A through F. These methods identify orders meeting certain

criteria.<sup>1</sup> Dr. Craig McCann ("McCann"), a data expert, retrospectively calculated the percentage of orders that met these criteria. Rafalski relied on McCann's calculations to assert the total percentage of orders that Rafalski believes should have been flagged and, assuming due diligence was not done to explain why the orders were innocuous despite being flagged, should have been reported to the DEA as suspicious and never left defendants' warehouses.

At trial, Rafalski read these results into the record. Rafalski offered opinions that because defendants shipped these orders without conducting due diligence and failed to report them to the DEA, defendants' systems for identifying, blocking, and reporting suspicious orders were deficient, and defendants did not maintain effective controls against diversion.

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<sup>1</sup> The methods do not purport to establish how a distributor would then conduct due diligence once an order is flagged or what would be necessary to dispel the suspicion arising from the order having been flagged. In other words, all the methods purport to do is flag orders, not provide a comprehensive roadmap that distributors could (or should) employ in determining whether the orders ultimately must be blocked. That said, Rafalski's opinions regarding the volume of suspicious orders that defendants supposedly shipped requires an assessment of their performance of due diligence, which he finds insufficient. Based on the insufficient documentation of due diligence that Rafalski discerns from the discovery materials, he infers that sufficient due diligence never happened. Thus, he employs an assumption, both in flagging orders and in tallying up suspicious orders distributed, that due diligence never dispelled the initial (flagged) suspicion of any order.

As explained below, defendants' Daubert challenge to Rafalski's testimony up to this point is misplaced. Defendants' criticisms of the flagging criteria (Methods A through F), the application of the criteria to the data (through McCann), and Rafalski's evaluation of defendants' suspicious order monitoring systems (referred to in the singular or plural as "SOMS"), very much go to the weight of his opinions, not their admissibility.

Not so for Rafalski's causation opinions, which are disconnected from a reliable methodology. Rafalski's challenged causation opinions include those that: (1) systemic failures by defendants to maintain effective controls against diversion were a substantial factor in causing diversion; and (2) all of the orders that defendants knew or should have known were suspicious were more likely than not to be diverted. Accordingly, the court must strike those opinions.

**a. Flagging Methods, Results Thereof, and SOMS Critique**

Defendants' Daubert challenge to Rafalski's flagging methods and the results thereof is misplaced, as is their Daubert challenge to Rafalski's opinion about whether defendants maintained adequate controls against diversion and ran a system that was effective at identifying, blocking, and reporting suspicious orders.



### 1. Flagging Methods Themselves

To the extent defendants bring a Daubert challenge to Rafalski's presentation of the methods themselves as possible ways to flag orders, it is not really a challenge to the methodology (how Rafalski identified possible flagging methods), but to the opinion (the list of possible flagging methods). Rafalski's presentation of Methods A through F merely identifies possible ways of completing part of a task: flagging orders that merit a harder look prior to fulfillment.

To identify possible methods, Rafalski relied on his experience and review of discovery materials and at least attempted to base his methods on systems that he observed while at the DEA or while reviewing the discovery materials in this case. In providing his list of possible flagging methods, Rafalski is not trying to arrive at some scientific or technical truth. He is merely saying that, based on his DEA experience and review of discovery in this case, Methods A through F are some of the potential (not mandatory) means that defendants could have used to identify orders that possibly should not have been shipped. Defendants' demand for more rigorous methodology for establishing the list of methods itself is unfounded.<sup>2</sup>

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<sup>2</sup> This is not at all to say that Rafalski's methods are particularly good ones or that the results of applying the methods were persuasive indicators of the level of suspicious orders placed with defendants. It is also not to say that the

## 2. Results of the Methods

Whether Rafalski's opinions constituting the results of his flagging methodologies are the product of reliable methodology is a related but distinct question. Defendants' challenge to the results (the application of Methods A through F to the shipment data), however, tends to ignore that "there are many algorithms that a Distributor could use to identify opioid orders as suspicious." In re Nat'l Prescription Opiate Litig., 2019 WL 3934490, at \*6. Rafalski freely acknowledged that there is no "one particular golden rule" on how to flag orders and that his methods are only a few among a "huge number" of different possible methods. (Tr. 5/26, at 82-84.) The reliability analysis is heavily informed by the background principle that there are innumerable ways to set flagging criteria. In this context, then, reliability means that the methods must meet the low bar of being among the innumerable permissible possibilities.

The accuracy of the methods in identifying orders that should not be shipped (and only those orders) is a separate question that has little to do with Daubert because a flagging method can be overinclusive (or underinclusive) and still be a permissible way to flag suspicious orders. Because defendants

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overlay of a no-due-diligence assumption was at all justified based upon the evidence. Those are not Daubert issues.

have failed to show that Methods A through F fall outside the vast realm of available flagging methods, the court does not discern an admissibility problem. The Daubert challenge ultimately makes the results out to be more than they are, skipping ahead to Rafalski's (inadmissible) opinions regarding the level of actual diversion in the City of Huntington and Cabell County and the connection between orders that he believes were not permissible to ship and the opioid epidemic in the City of Huntington and Cabell County.

Furthermore, it is worth noting that to the extent the results incorporate a no-due-diligence assumption (or some variation thereof), those results are bound up within a dispute of fact: Did defendants conduct due diligence? Rafalski's expertise bears on this dispute, but so does the rest of the relevant record. That is, whether many of the flagging results provide an even remotely accurate count of suspicious orders (both flagged and shipped) depends on a dispute for which there is conflicting evidence.

The attempt to resolve this factual dispute in the Daubert context leads to confusion. For instance, defendants argue that Rafalski's methods are unreliable because they ignore the crucial fact that prescribing rates increased over the years. Presumably, however, that would be a due diligence consideration

in Rafalski's methods once an order is flagged, not before.<sup>3</sup> It is true that the no-due-diligence assumption leads to setting aside very good explanations for orders that may be flagged and to a vastly overinflated number if the assumption is incorrect. But the assumption is not so severely unfounded as to cause the methods to run afoul of Daubert and make the results thereof inadmissible. See Masters Pharm., Inc. v. DEA, 861 F.3d 206, 218 (D.C. Cir. 2017) (noting that absence of records is sometimes evidence that activity did not occur).<sup>4</sup>

Defendants insist on the application of Daubert's (non-mandatory) factors to Rafalski's methods and their results, faulting Judge Polster for not applying those factors, and concluding that Judge Polster's opinion regarding the

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<sup>3</sup> It may well also be an important factor in setting thresholds (may justify a higher threshold), but the point here is that Rafalski does not appear to have ignored the prescribing rates as much as consider it part of a (subsequent) due diligence inquiry that he believes did not take place. Defendants' Daubert argument does not appear to be that Rafalski's thresholds were too low (and thus, unreliable) because they failed to consider prescribing increases. In any event, that is a weight argument.

<sup>4</sup> The permissible inference regarding the absence of a record is to be applied when the absence is "where an entry would naturally have been made if a transaction had occurred." Masters, 861 F.3d at 218. Because federal law does not require permanent retention of due diligence records (or even the creation of them), the application of this permissible inference is questionable for the finder of fact here. But as an expert witness, the scope of Rafalski's permissible inferences is greater and appears to encompass his no-due-diligence inference.

reliability of Rafalski's methods and their results "is neither controlling nor persuasive as applied here." (ECF No. 1398, at 2 n.1.) The court disagrees. Additionally, since the briefing here, Judge Polster has issued another Daubert ruling with respect to Rafalski, which the court also finds persuasive, including its assertion that "[p]articularly with respect to non-scientific experts, like Rafalski, 'the relevant reliability concerns may focus upon personal knowledge or experience.'" In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2021 WL 4060359, at \*5 (N.D. Ohio Sept. 7, 2021) (quoting First Tennessee Bank Nat. Ass'n v. Barreto, 268 F.3d 319, 335 (6th Cir. 2001)).

The flagging methods attempt to capture what is suspicious, a quality that inherently evades precision. This is not a scientific or engineering inquiry for which application of the traditional Daubert factors would be suitable. The court agrees that "it is precisely Rafalski's specialized knowledge and DEA experience that form the basis for the reliability of his opinions" regarding the flagging methods. Id.

Furthermore, defendants' complaint about what they consider "a 400% error rate" among the different methods is not well taken. (ECF No. 1386, at 6.) Again, Rafalski was not trying to arrive at a scientific or engineering truth. The divergence in the results reflects the vagueness of the duty to identify

suspicious orders and the lack of guidance in how flagging systems should operate, not a faulty methodology on Rafalski's part. Had Rafalski presented only one method, the criticism doubtless would be that there is no one method. True, the methods present vastly different levels of flagging. In other contexts, that certainly may present a Daubert problem. In this one, it goes to weight.

It is also true that, by expressing a preference for Method A, Rafalski's opinions regarding Method A start to approach something objectionable under Daubert. But Rafalski's belief in the accuracy of Method A appears to derive from his belief that defendants' efforts to conduct due diligence were slim to none and that one suspicious order immerses the customer account in suspicion until there is due diligence. While the record contains evidence of consistent due diligence, that does not render Rafalski's opinion about the lack of due diligence or his incorporation of a no-due-diligence assumption inadmissible.

Defendants label the methodologies as "created for litigation." (Id. at 12.) In a sense, this is true in that Rafalski conceded that he did not use them as a DEA investigator and that he developed his list of alternative flagging methods for this case. (Tr. 5/26, at 222.) But defendants' overall label is a stretch. It ignores that Rafalski clarified as follows:

I didn't create these. I tried to use methodologies that were similar to the methodologies that were -- that I -- that I discovered or found while doing this case. So, it wasn't something that I created. Although they're not exactly the same, they're, you know, the best that we could do to recreate those methodologies used by the defendants.

(Tr. 5/26, at 223.)<sup>5</sup>

Judge Polster has rightly rejected the argument that "Rafalski's SOMS opinions cannot possibly be reliable unless he followed the exact same methods and procedures as he would in conducting a DEA field investigation." In re Nat'l Prescription Opiate Litig., 2021 WL 4060359, at \*5. Defendants' invented-for-litigation argument is essentially the same argument. Moreover, "an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion." Tyree v. Bos. Sci. Corp., 54 F. Supp. 3d 501, 518 (S.D.W. Va. 2014), as amended (Oct. 29, 2014). The provenance of Methods A through F is an issue of weight, not admissibility.

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<sup>5</sup> Defense counsel's next question ignored the clarification:

Have you used these style -- have you taken these stylized illustrations that were created for litigation and tried to publish them so they could be peer-reviewed and available for criticism and use if they were actually valuable?

(Tr. 5/26, at 223 (emphasis added).) But the witness had the right to clarify his testimony despite counsel's rejection of it.

In supplemental briefing on their renewed motion, defendants also argue that the results of Rafalski's flagging methodologies are inadmissible because plaintiffs failed to call McCann, who ran the numbers, back to the witness stand to sponsor his calculations. This was despite repeated assurances on the record that plaintiffs would recall McCann. Plaintiffs respond that they understood the court to have ruled that McCann need not be recalled because Federal Rule of Evidence 703 allows an expert to base his testimony on matters he has observed or been made aware of (such as McCann's calculations).<sup>6</sup>

Under Rule 703, the court deemed Rafalski's testimony admissible without McCann's independent sponsorship of his calculations. The court sticks with that ruling and rejects defendants' argument that Rafalski could not testify to the results of the calculations that he asked McCann to run. That

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<sup>6</sup> In response to the objection that Rafalski could not testify to the results of McCann applying the methods to the shipment data, the court ruled as follows:

I'm going to cut this short and rely on Rule 703, which the first sentence says an expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. He's been aware of this data that comes from Dr. McCann, apparently, or is consistent with what Dr. McCann said and I think that since it's the basis of an expert opinion, it's permissible, and I'm going to overrule the objection and let him go ahead.

(Tr. 5/26, at 50-53.)



said, the court's ruling does not get plaintiffs around the problem that their failure to recall McCann contradicted their repeated representations that they would do so. This failure was, at best, curious.

On the other hand, plaintiffs' construction of the court's bench ruling as an absolute free pass on recalling McCann was not patently unreasonable. More importantly, perhaps, defendants did not press the court in the context of trial for a ruling on the need to recall McCann, choosing instead to make the failure to recall McCann part of their Daubert challenge to Rafalski's testimony.<sup>7</sup>

### **3. Diversion-control Failures**

Rafalski's opinions that defendants failed to design effective systems to prevent diversion and failed to maintain effective controls against diversion are arguably legal conclusions that are unhelpful. On the other hand, the opinions do not explicitly reference the law and can be perceived as opinions that defendants failed to fulfill certain tasks as a matter of fact, not as a matter of law. In any event, the trier

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<sup>7</sup> Defendants easily could have stepped outside the Daubert context and brought the issue squarely before the court for a ruling on whether plaintiffs needed to honor their representations and recall McCann as a matter of fundamental fairness (not as a matter of Daubert).

of fact here (the court) understands that Rafalski's opinions, even if legal ones, are not controlling.

These opinions are based on the results of Rafalski's flagging methods, which he contends show (together with his conclusion that due diligence never happened), that varying levels of suspicious orders were shipped. One important point is that the analysis here undertaken departs significantly from that undertaken in connection with Masters.<sup>8</sup>

In Masters, the distributor's conduct was judged against the failures evident when applying its own SOMS. 861 F.3d at 214-16. The court noted that Masters Pharmaceutical's SOMS flagged orders that could be considered suspicious "[a]s a matter of common sense and ordinary language," but the court did not purport to mandate that system for other distributors. Id. at 216-17. Here, the analysis does not judge defendants'

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<sup>8</sup> During direct examination, Rafalski's analysis was repeatedly referred to as an "investigation," and Rafalski characterized it as follows:

I think you've asked me essentially, Your Honor, to do the same thing I did when I was working with the DEA. And that's to examine those same types of records and documents that are up on the screen in regards to the three defendants, AmerisourceBergen, Cardinal, and McKesson, and come to the same factual findings on whether these three companies maintained effective controls to prevent the diversion of controlled substances . . . ."

(Tr. 5/26, at 29-30.)

conduct against its own SOMS. This is obvious for Methods A and B, which there is no evidence that defendants ever used. So, even if Method A is analogous to what was used in Masters, applying the Masters SOMS here is not analogous to what was done in Masters itself (especially with the overlay of a no-due-diligence assumption).<sup>9</sup>

As for Methods C through F, although Rafalski testified that he attempted to base those on defendants' systems, he did not come close to replicating those systems exactly and did not establish that those flagging criteria were in place for the entire relevant time period. It is undisputed that, unlike in Masters, the analysis here was not a review of a distributor's compliance with its own SOMS.

As stated above, however, the court agrees with Judge Polster that whether Rafalski's analysis matches what the DEA would have done is not an admissibility issue. See In re Nat'l Prescription Opiate Litig., 2021 WL 4060359, at \*5. Rafalski compared the results of his flagging methods, including the one he believes is appropriately aggressive at flagging orders

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<sup>9</sup> Additionally, the record here is far different than the one in Masters, which established that Masters (1) failed to clear with due diligence or report to the DEA orders that its own SOMS flagged (to the tune of hundreds of orders); (2) deleted or reduced flagged orders to get around its SOMS; and (3) shipped orders when customer explanations confirmed the suspicion that the orders were being diverted. 861 F.3d at at 215.

(Method A), against the shipments that defendants completed. Based on the large (sometimes unbelievably large) gap between what was shipped and what Rafalski believes should have been shipped, he finds the systems and the overall effectiveness of controls deficient.

Again, the linchpin here (at least for Method A)<sup>10</sup> is Rafalski's conclusion that defendants systematically failed to conduct due diligence, which is largely a factual dispute. Rafalski's analysis seems to have been that because a number of different flagging angles indicate suspicious orders, and because there was chronic insufficient due diligence prior to shipping those orders, there was a failure to maintain effective controls. There is a factual dispute about defendants' exercise of due diligence, and the Daubert context is not the right one for resolving it.

Defendants further point out that Rafalski did not explain why their own SOMS, as operated, were deficient and instead merely testified that running other, hypothetical systems suggested the shipment of suspicious orders. Defendants also

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<sup>10</sup> In fixing the threshold for all time, Method B also applies a no-due-diligence assumption of sorts because the reason the threshold cannot increase is apparently that no due diligence is ever done to justify a threshold increase. Plaintiffs state that Rafalski's opinion that defendants did not conduct due diligence and his opinion that subsequent orders cannot be shipped until due diligence occurs "apply across all of Mr. Rafalski's methodologies." (ECF No. 1396, at 10 n.1.)

point out that the no-due-diligence assumption conflicts with extensive evidence to the contrary and that Rafalski did not reconcile his opinions with that evidence. These points carry weight, but not in the Daubert context.<sup>11</sup>

**b. Causation Opinions**

Defendants further challenge Rafalski's causation opinions, which are as follows:

1. Defendants' systemic failures [to maintain effective controls against diversion and to run adequate SOMS] were a substantial factor in the diversion of controlled substances into the illicit market; and
2. All orders that defendants knew or should have known were suspicious were likely (more likely than not) to be diverted into the illicit market in the City of Huntington and Cabell County.

These opinions are inadmissible under Rule 702 and Daubert for lack of a reliable methodology.<sup>12</sup>

The first causation opinion takes what Rafalski perceives as shortcomings in defendants' SOMS and due diligence and makes the unexplained leap of identifying such shortcomings as a factual cause of diversion. Plaintiffs suggest that this causation opinion naturally "flows" from the opinion that there were deficiencies with defendants' SOMS and due diligence. (ECF

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<sup>11</sup> Rafalski's opinion that defendants' purported failures to design and operate effective SOMS and to maintain effective controls against diversion were "systemic" is also admissible.

<sup>12</sup> The court need not address whether Rafalski is qualified to provide these opinions.

No. 1396, at 2-3.) If the flow is so natural, however, there would be no need for expert testimony on causation (and such testimony would accordingly be unhelpful). The reality is that establishing a causal link between purported deficiencies in controlling against diversion and actual diversion requires expert analysis not employed here.

The court agrees with defendants that this opinion appeared out of thin air. (See ECF No. 1386, at 20 ("Mr. Rafalski was not even asked to explain how he arrived at this "substantial factor" opinion. Mr. Rafalski never discussed, much less explained, the methodology he used to reach his opinion—nor did he provide any demonstration that the methodology (if there was one) is generally accepted and reliable.").) Rafalski did not identify a pharmacy that was engaged in diversion and agreed that distributions matched prescriptions. He offered no evidence to show that pharmacies were filling prescriptions not issued pursuant to valid doctor-patient relationships, as in the case of Internet pharmacies.

The opinion appears to be based on speculation. It is speculative to say that just because orders that were flagged or that should have been flagged (even a large amount) were shipped without due diligence, there was any diversion at all caused by the lack of flagging or lack of due diligence. All Rafalski could really say on this record is that it appears that

distributions resulted in diversion at some point, not that defendants' distributions were themselves diverted.

The second causation opinion attempts to transform orders that were purportedly suspicious into orders that were more likely than not to be diverted. The court cannot discern the presence of a reliable methodology for this opinion either. Importantly, Rafalski did not attempt to determine the level of diversion that actually occurred. Equating suspicious orders with those more likely than not to be diverted is an unreliable, speculative way to estimate diversion. See Masters Pharm., Inc., 80 Fed. Reg. 55,418, 55,480 (Drug Enf't Admin. Sept. 15, 2015) ("[T]o conclude that an order is suspicious, the information presented to the distributor is not required to establish, to a statistical certainty, that a pharmacy was likely diverting controlled substances. Rather, the evidence must only create a suspicion, a standard which is less than that of probable cause."). In short, Rafalski did not apply a discernible, reliable methodology to support an equation between suspicion and actual diversion.<sup>13</sup>

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<sup>13</sup> An overbroad understanding of diversion may be one source of the disconnect here. As the court understands it, Rafalski's testimony was that diversion means that pills eventually "fall into illicit hands." (Tr. 5/26, at 76.) Under that extremely broad understanding of diversion, it is perhaps more reasonable to infer that because there is an opioid epidemic, which necessitates pills falling into illicit hands, some of the pills (perhaps many or even most—we do not know from the evidence)

The court does not doubt the sincerity of Rafalski's beliefs regarding causation. And his noteworthy experience on the ground in federal public service likely informs those beliefs. As here, however, sincerely held beliefs informed by extensive, honorable service do not necessarily pass Daubert muster. Because they are not based on a reliable methodology, the causation opinions are inadmissible, and the court must strike them.

**IV. Conclusion**

For the reasons expressed above, defendants' motion to exclude (ECF No. 1385) is **GRANTED** in part and **DENIED** in part.

The Clerk is directed to send a copy of this Memorandum Opinion and Order to those counsel of record who have registered to receive an electronic NEF.

**IT IS SO ORDERED** this 27th day of June, 2022.

ENTER:

A handwritten signature in black ink, reading "David A. Faber", is written over a horizontal line.

David A. Faber

Senior United States District Judge

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that defendants shipped someday, somehow fell into the wrong hands.